

REMARKS

Claims 35-40 are pending in this application, with claims 35 and 38 being the independent claims. Claims 1-34 were previously canceled. Claims 35, 37-38, and 40 have been amended. Reconsideration is respectfully requested in view of the foregoing amendments and following remarks. The remarks are believed to be fully responsive to the Office Action mailed April 24, 2009 and to render the claims at issue patentably distinct over the cited references and in condition for allowance.

I. Rejections Under 35 U.S.C. 112, first paragraph

A. New Matter

In the Office Action of April 24, 2009, the Examiner rejected claims 35-40 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. More specifically, the Office Action provided that the claim recitations “at least more than about 10 weight percent long carbon chain prior to hydrolysis” and “lipid comprises at least more than about 10 weight percent long carbon chain prior to hydrolysis” of amendments filed August 9, 2006 and August 5, 2008, respectively, introduced new matter. Applicants have amended independent claims 35 and 38, and claims 36-37 and 39-40 by dependency thereon. Such amendments are believed to overcome the new matter rejection.

Amended claim 35 relates to providing a composition for topical application, wherein said composition increases substantivity and neutralizes an acid gelling agent. The method comprises the step of neutralizing the gelling agent with an effective amount of said composition. The composition comprises polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products

of hydrolysis of a lipid comprising jojoba oil, wherein said lipid comprises at least 6 weight percent long carbon chain unsaponifiable material prior to hydrolysis.

Support for the amended claim language –wherein said lipid comprises at least 6 weight percent long carbon chain unsaponifiable material prior to hydrolysis-- may be found in the Table at p. 10-12 of the as-filed Application.

Amended claim 38 clarifies that the long carbon chain material comprising at least 18 carbons in length is unsaponifiable. Support for this claim may be found in the as-filed Application at p.7, lines 19-21. Applicants submit that these claim amendments overcome the new matter rejection and respectfully request its withdrawal.

B. Non-enabling

Claims 35-40 were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly being directed to non-enabling subject matter. Specifically, the Examiner rejected claims 35-40 on the basis that compositions comprising the products of hydrolysis of any lipids other than jojoba oil are not enabled. The Examiner does admit that the disclosure enables making and using the subject matter of claims 35-40 for jojoba oil. As these claims are enabled, because the Examiner failed to meet his burden of establishing a reasonable basis to question the enablement provided for the invention, and because the enablement rejection is untimely, Applicants respectfully traverse the Examiner's rejection.

All questions of enablement are evaluated against the claimed subject matter. MPEP 2164.08. As stated above, amended claim 35 is directed to providing a composition for topical application, wherein said composition increases substantivity and neutralizes an acid gelling agent. The method comprises the step of neutralizing the gelling agent with an effective amount of said composition. The composition comprises polar hydrophilic salts and non-polar

unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil, wherein said lipid comprises at least 6 weight percent long carbon chain unsaponifiable material prior to hydrolysis. Amended claim 38 adds the feature that the long carbon chain material comprising at least 18 carbons in length is unsaponifiable. Dependent claims 36 and 39 are directed to lipids in addition to jojoba oil and dependent claims 37 and 40 directed to percent by weight of unsaponifiables.

The Examiner found a lack of enablement for lipids other than jojoba oil on the basis that "Applicants admit that the starting material will affect the product of hydrolysis in terms of saponifiables and non-saponifiable contents..." and "[i]t is not clear from the specification what are the hydrolysis content of any other lipids, the ratio of saponifiable and non-saponifiable, and their effects." (Office Action, p. 5, lines 18-21). She further notes: "It is not obvious from the disclosure of hydrolyzed jojoba oil if the other hydrolyzed lipids including those of plant, animal, and fungal origin will provide the same hydrolysis products and work in the same way regarding increasing substantive skin benefit." (Office Action, p. 5, lines 6-9). Notably however, the claims do not specify the hydrolysis content of any lipid (including jojoba oil) or the ratio of saponifiable and non-saponifiable. The disclosure clearly describes and enables the claimed lipids comprising at least 6 weight percent long carbon chain unsaponifiable material prior to hydrolysis (See the Table on pp. 10-12 of the as-filed application which includes the weight percent of unsaponifiable material of jojoba oil as well as of all the lipids claimed in dependent claims 36 and 39). That the products of hydrolysis of these lipids comprise polar hydrophilic salts and non-polar unsaponifiables as claimed is enabled at p. 13, lines 26-29 of

the disclosure. The hydrolysis method needed to practice the invention is well known. Therefore, enablement is commensurate in scope with claims 35-40.

With respect to the claimed effects of increasing the substantivity and neutralizing of an acid gelling agent with the hydrolysates of the claimed lipids, Applicants' Specification provided working examples using jojoba oil. The Office Action admits enablement with respect to jojoba oil. MPEP 2164.04 states that, in order to make a rejection based on nonenablement, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the invention. Quoting from In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), MPEP 2164.04 states: "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure."

The Examiner has failed to make any findings of fact to support her conclusion that there is no enablement for the hydrolysates of the lipids other than jojoba oil to increase substantivity and neutralize an acid gelling agent, or that hydrolysis of the other lipids does not result in polar hydrophilic salts and non-polar unsaponifiabiles as claimed. She has not stated why one would not expect to be able to extrapolate the jojoba examples to the other lipids. The conclusory statements under each of the In re Wand, 8 USPQ2d 1400 (Fed. Cir. 1988) factors are insufficient. The reference to chemicals and chemical compounds (Office Action, p. 6, lines 1-9) is inapposite as the specific hydrolysis content of the lipids (including jojoba oil) and the

ratio of saponifiable and non-saponifiable in the hydrolysates is not claimed. Therefore, she has not met her burden.

Moreover, as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. The Examiner is impermissibly trying to limit the scope of the application solely to the jojoba examples disclosed in the application. Accordingly, Applicants submit that a skilled artisan could readily make and use the subject matter of Claims 35-40 without undue experimentation. As such, these claims are readily enabled.

Applicants also submit that this enablement rejection is untimely. As stated in MPEP 2164.04, “[i]n accordance with the principles of compact prosecution, if an enablement rejection is appropriate, the first Office Action on the merits should present the best case....” The first Office Action on the merits issued on September 25, 2007. This first Office Action did not include an enablement rejection. A Final Rejection that issued June 5, 2008 also did not include an enablement rejection. Lipids other than jojoba oil were claimed in the as-filed application. Therefore, to raise such a rejection now is repugnant to the principles of compact prosecution. Therefore, in view of this and the foregoing reasons, reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejections is respectfully requested.

II. Rejection under 35 U.S.C. 112, second paragraph

In the Office Action of April 24, 2009, claims 35-40 were rejected as indefinite in use of the terms “at least more than about” and “at least more than 10%”. Applicants have amended independent claims 35 and 38 and claims 36-37 and 39-40 by dependency thereon to clarify the claims.

In addition, the Office Action provides that the claims are confusing because claims 35 and 38 recite lipid comprising jojoba oil that is implied to be derived from the plant *Simmondsia chinensis* and claims 36 and 39 recite that the lipid of claims 35 and 38, respectively, comprises material selected from shark-liver oil, dog fish oil and oils from fungi. The Office Action questions how lipids comprising jojoba oil will be derived from animal or fungal origin.

In response thereto, Applicants note that the transitional term "comprising", as used in claims 35 and 38 is inclusive or open-ended (MPEP 2111.03) and therefore the lipid includes jojoba oil but does not exclude other oils. Claims 36 and 39 dependent thereon are directed to such other oils as evidenced by use of the "further comprising" language. Therefore, properly construed, the rejected claims do not recite that the jojoba oil is derived from animal or fungal origin. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. 112, second paragraph rejection.

III. Rejection Under 35 U.S.C. 103(a)

In the Office Action of April 24, 2009, claims 35-40 were rejected under 35 U.S.C. 103(a) as obvious over FR 2471775, published June 26, 1981 to Assignee, L'Oreal (hereinafter "FR 2471775") in view of U.S. Patent No. 6,280,746 issued on August 28, 2001 to Arquette et al. (hereinafter "Arquette") as prior art under 35 U.S.C. 102(e).

As recognized in the Office Action, FR 2471775 does not teach hydrolysis of oils or neutralizing of a gelling agent as claimed. Arquette, as disqualified under 35 U.S.C. 103(c) below, cannot supply that deficiency. Applicants hereby disqualify Arquette under 35 U.S.C. 103(c) as prior art by providing the following clear and conspicuous statement under the following separately labeled section:

DISQUALIFICATION OF ARQUETTE UNDER 35 U.S.C. 103(a)

This Application Serial No. 10/611,775 and U.S. Patent No. 6,280,746 to Arquette et al. were, at the time the invention of Application Serial No. 10/611,775 was made, owned by International Flora Technologies, Ltd.

Accordingly, Arquette is disqualified from being used in a rejection under 35 U.S.C. 103(a) against the claims of this Application either alone or in combination with FR 2471775. Accordingly, withdrawal of the 35 U.S.C. 103(a) rejection is respectfully requested.

IV. Double Patenting

Claims 35-40 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,435,424 issued October 14, 2008 to Copeland et al. (hereinafter "Copeland") in view of Arquette. Applicants hereby submit a terminal disclaimer and fee in compliance with 37 CFR 1.321(c) to obviate the double patenting rejection.

V. Conclusion

In view of Applicants' remarks, Applicants respectfully submit that the application is now in condition for allowance, and such allowance is therefore earnestly requested. Should the Examiner have any questions or wish to further discuss this application, Applicants request that the Examiner contact the Applicants' attorneys at the below-listed telephone number.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent abandonment on this application, please consider this as a request for an extension for the

required time period and/or authorization to charge Deposit Account No. 50-2091 for any fee which may be due.

Respectfully submitted,
INGRASSIA FISHER & LORENZ, P.C.

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By: /JANINE RICKMAN NOVATT/
Janine Rickman Novatt
Reg. No. 32,593
(480) 361-0466
Customer No. 77037